Thermal Angel®

Blood and IV Fluid Infusion Warmer

TA-200 Frequently Asked Questions

---

1. **Is the Thermal Angel TA-200 compatible with any IV tubing?**
   Yes. The Thermal Angel TA-200 is compatible with any tubing set that utilizes a standard luer fitting.

2. **Can I give medications through the Thermal Angel TA-200?**
   Yes. A note of caution: approximately 10 cc of fluid occupies the unit at any given time. Therefore, meds with a short half-life should be administered distal to the unit, as close to the infusion site as possible. Most extension sets have injection ports for that purpose.

3. **Does the housing of the Thermal Angel TA-200 get hot?**
   No. You will feel the housing get warm, but it will not get hot. In fact, the manufacturer recommends securing the Thermal Angel TA-200 to the patient and using it as a wrist board or joint splint.

4. **Will a unit failure occlude fluid flow?**
   No. A failure in the unit will merely cause ambient temperature fluid to flow through the unit. There are no barricades or checkvalves inside the Thermal Angel TA-200 fluid path that would occlude flow under any circumstances.

5. **Will an alarm sound during overheat or malfunction?**
   No. The LED located on top of the end cap will either blink (error) or not illuminate (insufficient battery or blown fuse in unit) during a malfunction. As a precaution, an independent failsafe will activate in the event a possible overheat is detected. If the incoming fluid temperature exceeds 47°C (116.6°F) and the power is connected, the failsafe circuit will be activated. Activation of the failsafe circuit will result in permanent operational termination. Note: fluid will continue to flow, even if the heater is not functioning.

6. **How fast and how slow can I infuse fluids through the Thermal Angel TA-200?**
   The Thermal Angel TA-200 is designed to operate under pump or gravity flow. The limiting factors are catheter size and inner diameter of the luer connection. The Thermal Angel TA-200 will strive to achieve 38°C (100.4°F) ±3°C at a flow rate of 2 to 150 ml/min given a fluid input temperature of 20°C (68°F) with a fully charged TA-BCE Battery.

7. **How much heat is lost after leaving the outlet port?**
   There are many variables that affect heat loss. The primary variables are flow rate, length and thickness of extension tubing, and ambient external temperature. To minimize heat loss, the Thermal Angel TA-200 was designed to be placed as close to the infusion site as possible. Therefore, a short 6 to 9 inch extension set is recommended such as the TA-9EXT.

8. **Can I change the temperature?**
   No. The nominal outlet temperature of 38°C (100.4°F) is set during manufacturing. Any attempts by the end user to alter the discharge temperature will damage the unit and will void the warranty.

9. **Does heating blood with the Thermal Angel TA-200 cause hemolysis?**
   The effects of heating refrigerated or cooled blood with the Thermal Angel TA-200 have been evaluated and the amount of cell lysis has been shown to be none or not clinically significant.

10. **How many units of blood can I safely infuse through the Thermal Angel TA-200?**
    The Thermal Angel TA-200 has been evaluated utilizing standard blood administration sets. The filter on these sets is the limiting factor in determining the maximum number of units allowed through one device. Laboratory tests have demonstrated three (3) to four (4) units of blood can be successfully administered before the filter is occluded. At this point, the administration set should be discarded, as should the Thermal Angel TA-200. Note: Multiple TA-BCE Batteries may be needed for warming of this much blood.

11. **I have a patient who has had an IV for seventy-two (72) hours and I need to change tubing and site location. Can I keep using the same Thermal Angel TA-200?**
    The manufacturer recommends that the health practitioner think of the Thermal Angel TA-200 as an extension of the IV tubing. Therefore, when one must be changed, so should the other.

12. **If I have to stop flow to change IV bags, especially when blood is hanging, should I disconnect the Power Cable?**
    Disconnecting the Power Cable, in effect, turns the heaters off. If left connected, the heaters will cycle to maintain a 38ºC (100.4ºF) fluid temperature inside the device. Blood samples have been evaluated with the heaters on at stop flows for one minute and repeated at a stop

Estill Medical Technologies, Inc.
4144 N. Central Expwy. Suite 260 Dallas, Texas 75204
(214) 561-6001 Fax: (214) 561-1930 Toll Free: (877) 354-0286 www.thermalangel.com

flow of five minutes with little to no effect. Stop flow conditions greater than five minutes with the power left connected have not been evaluated.

13. Can this device be used in an MRI?
No. The Thermal Angel TA-200 has not been evaluated for use within a MRI.

14. Can I resterilize and reuse the Thermal Angel TA-200?
No. The Thermal Angel TA-200 unit is a single patient use, disposable item. Do not resterilize or reuse the Thermal Angel TA-200.

15. Do I throw everything away?
The Battery, Battery Bag, Battery Charger and Power Cable are reusable. However, the Thermal Angel TA-200 unit is a single patient use, disposable item, and should be disposed of along with the IV line set and 9 Inch Extension Set.

16. Can the Thermal Angel TA-200 be used in conjunction with an IV pump?
Yes. The Thermal Angel TA-200 works with any known IV pump, up to the maximum flow rate of 150 ml/min. It is normally placed in-line distal to the pump.

17. How long will the battery last?
Battery life is directly related to the temperature of the fluid to be infused and the flow rate. The battery power is consumed at the fastest rate with high flows and low input temperature fluids. Therefore, lower flow rates and warmer fluid will yield a longer battery life and, conversely, higher flow rates and colder fluid yield a shorter battery life. With a fluid input temperature of 20°C (68°F), a fully charged TA-BCE Battery will last through approximately 2 to 4 liters of IV fluid at various flow rates. With a fluid input temperature of 10°C (50.0°F), a fully charged TA-BCE Battery will last through approximately 1 to 3 units of blood at various flow rates.

18. What is the price of the Thermal Angel TA-200 and accessories?
Pricing is available by calling (877) 354-0286 or filling out a form online at www.ThermalAngel.com.

19. Is the Thermal Angel TA-200 latex-free?
No. Although the Thermal Angel contains no latex that comes into contact with the patient, administrator or fluid path, there is a silicone sealant inside the end cap that contains some natural rubber latex.

20. Can the Battery be connected to the charger while using the Thermal Angel TA-200?
Charging the Battery and powering the Thermal Angel TA-200 are two separate operations. Do not charge the Battery while the Thermal Angel TA-200 is in operation. Disconnect the Battery Charger from the Battery during use of the Thermal Angel TA-200.

21. Does the Thermal Angel TA-200 have FDA clearance?
Yes. Estill Medical Technologies, Inc. has received 510(k) clearance (#K012031) from the U.S. Food and Drug Administration (FDA) to market the Thermal Angel TA-200 as a blood and IV fluid warmer.

22. Does the Thermal Angel TA-200 meet AABB regulations for blood warming devices?
Yes. The Thermal Angel TA-200 meets the American Association of Blood Banks (AABB) Standards, outlined in Section 3.8 “Warming Devices for Blood and Components” of the 23rd edition of *Standards for Blood Banks and Transfusion Services*.

23. Is the Thermal Angel TA-200 reimbursable?
Yes. Although the Thermal Angel TA-200 does not have a line item reimbursement code associated with its use, many facilities are including the Thermal Angel TA-200 under a lump sum amount associated with a particular service. Additionally, other reimbursement mechanisms exist such as the use of coding modifiers and patient charging. Please consult with your coding/reimbursement liaison for the best possible solution.

24. Is the Thermal Angel TA-200 certified for flight?
The Federal Aviation Administration (FAA) requires that all onboard electrical equipment be compliant with FCC regulations (47 Code of Federal Regulations Section 15(b)) for unintentional Radio Frequency Interference (RFI). The Thermal Angel TA-200 complies with these regulations and may be safely used onboard any aircraft operating in the United States. This laboratory testing is not to be confused with “Flight Testing”, as the FCC and RFI testing was performed in a controlled laboratory setting and not onboard an aircraft.